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EXAMINER

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ART UNIT

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1615
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Art Unit: 1615

The restriction Requirement is made Final.

Claims 32,40,41 require on additional search in view of scope (40,41) and equipment (32) considerations.

Claims 1-33,42-64,71 are rejected under 35 U.S.C. 103 as being unpatentable over WO 96/08243 taken together with either chem. Ab. 132:83528 or Chem. Ab. 126:229547 or Pentikainen Article.

The claims specify a general "biphasic" release rate which is considered to be enabled by the cited Prior Art tablet preparations. The core and layers in which metaform in is embedded are equivalent in the composition of the claims and those of the primary reference i.e. use of celluloses and all hydrophobic and hydrophilic polymers being known to the art. The secondary reference descriptions of variation in choice of polymers and compression conditions to achieve certain release such rates obvious to use in the primary reference tablets. Note AUC values of Pentikainen Publication.

In view of the close similarity of the materials used in compounding HPMC, etc., it is incumbent upon the applicants to demonstrate improved "biphasic" release in comparison with the compositions of the primary and secondary references.

Claims 1-33,42-64,71 are rejected under 35 U.S.C. 112, paragraph 2.

The claims do not point out and distinctly describe a solid dispersion in terms of improved physical properties which the specification reports as being the improvement over Prior Art drug solid dispersion.

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The comparative examples indicate that dissolution performance, improved stability and other features such as are expressed as MDC or AUC values are necessary to point out the invention and thus these descriptive terms are necessary to appear as claim limitations.

The terms "phase" and "biphasic" are unclear. The terms designate solid/liquid or solid solution distinctions, but a geometry wherein small particles are embedded in a larger carrier matrix of a different material is not defined. The limitations of claim 9 appear to be relevant to correct scope for claim 1. Pellets of a definite physical construction, i.e., the makeup of a working example product are suggested as necessary limitations.

The geometric forms which result from following the working example procedures yield results such as that of Table 1 at page 44. Thus, the claims must express the layers and size relationships of inner particles and matrix carrier. The "inner" and "outer" "solids" of claim 1 are possibly completely non-correspondent with the hydroxy celluloses and mechanical steps used in the working examples.

An analysis of the working example tablets using microscopy or other instrumental methods is not presented to confirm a clear structure for the inner and outer layers or particles.

Reference (L) is cited to complete the record.

Kulkosky/LR

March 19, 2001



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